IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company), **Plaintiffs,** **v.** **MIKE HILGERS, in his official capacity as ATTORNEY GENERAL OF THE STATE OF NEBRASKA,** **Defendant.**	**Case No. 4:25-cv-03089** **BRIEF IN SUPPORT OF MOTION TO DISMISS**

Defendant Michael T. Hilgers, Attorney General of Nebraska, submits this brief in support of his Motion to Dismiss. Plaintiffs have failed to state a claim upon which relief can be granted and thus their Complaint should be dismissed.

INTRODUCTION

Plaintiffs—drug manufacturers who participate in the federal 340B discount drug program—obviously feel aggrieved by perceived abuses and alleged noncompliance with that program's regulatory safeguards. But this lawsuit, in which Plaintiffs take aim at a Nebraska statute and Nebraska law enforcement (rather than

the federal program itself, the federal entities that could mitigate the alleged harms, or the wrongful actors themselves) is a clear case of misdirected anger. This Court should not indulge the Plaintiffs' temper tantrum.

At the heart of Plaintiffs' complaint are allegations of diversion. In short, Plaintiffs accuse healthcare providers (to whom they are required, as participants in the 340B program, to sell discounted pharmaceuticals) of conspiring with commercial pharmacies to resell those discounted drugs at full price to non-340B patients. This, they claim, allows the providers and pharmacies to obtain windfall profits, ostensibly at Plaintiffs' expense.

The federal statute that governs the 340B program explicitly prohibits diversion. And it contains numerous mechanisms designed to both prevent and remediate diversion if and when it happens. But, according to Plaintiffs, after the federal government changed its interpretative guidance regarding the 340B program in the 2010s, diversion became rampant.

As part of their response to this alleged explosion of diversion, Plaintiffs have decided to sue not the diverting facilities or the federal government, but rather the *Attorney General of Nebraska*, seeking to enjoin him from enforcing a *Nebraska law*. They have made this curious choice even though it is a *federal law* that imposes the mandate to sell drugs to certain healthcare providers at a discounted rate. Notably, Plaintiffs' participation in the federal program is entirely voluntary—they could opt out of 340B (and thus end the possibility of diversion *entirely*) at any time. And, further, that federal program contains numerous anti-diversion provisions that

Plaintiffs could avail themselves of. Or they could ask the federal government to step up its anti-diversion enforcement efforts.

Instead, Plaintiffs have chosen to take aim at a Nebraska statute that neither authorizes diversion nor shields those who engage in the practice. That law—L.B. 168—is a mere supplement to the federal 340B regime, one designed to ensure indigent, rural, and other underserved Nebraskans have access to critical healthcare in their own communities. L.B. 168 simply tells drug manufacturers that if they are going to participate in the 340B program, they must deliver 340B drugs purchased by qualifying healthcare facilities to any pharmacy with which the purchasing facility has a contractual distribution relationship. And the manufacturers cannot impose onerous conditions designed to deter or interfere with those distribution relationships.

Plaintiffs assert that L.B. 168 is unconstitutional. They first claim it is an uncompensated taking. But Plaintiffs *choose* to participate in the 340B program; they could stop doing so at any time. And Nebraska's law functions only in tandem with the federal scheme; it imposes obligations only on 340B participants. Next Plaintiffs argue Nebraska's law is preempted. But that claim is foreclosed by Eighth Circuit precedent. They then try their luck with the dormant Commerce Clause, but L.B. 168 does not discriminate and applies only to conduct that takes place within Nebraska. Finally, they allege that the statutory language is vague. But L.B. 168 clearly outlines to whom the manufacturers must deliver their drugs—any pharmacy compliant with

federal law that has a distribution contract with a qualifying 340B health care provider (a "covered entity").

None of these theories are legally or factually viable. Accordingly, because Plaintiffs have failed to plausibly allege a claim for which relief can be granted, their Complaint should be dismissed.

BACKGROUND

I. In an effort to ensure both that low-income Americans have access to pharmaceuticals and that the healthcare providers who treat them can continue to provide their critical services, the federal government offers drug manufacturers a choice: If they want to sell their products to Medicare and Medicaid patients, they must agree to participate in what is known as the 340B program.[1] Filing No. 1, ¶ 3; *see Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 455 (D.C. Cir. 2024).[2] By participating in the 340B program, drug manufacturers agree to sell drugs at discounted prices[3] to "covered entities"—certain health care providers that treat impoverished or otherwise underserved populations. 42 U.S.C. § 256b(a)(1), (a)(4).

The United States Department of Health and Human Services ("HHS") and Health Resources and Services Administration, the federal entities that administer

[1] The "340B" name is a reference to a section of the Public Health Service Act. *See* Pub. L. No. 78-410, 58 Stat. 682 *codified at* 42 USCA Ch. 6A; *see also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943 (1992 amendments to the Public Health Service Act) *codified at* 42 U.S.C. § 256b.

[2] *See also* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28643, 28643 (quoting H.R. Rep. No. 102-384(II), at 12 (1992)).

[3] According to a rebate percentage calculated under the section 192(c) of the Social Security Act, 42 U.S.C. § 256b(a)(2)(A).

the 340B program, have issued interpretive guidance indicating that covered entities can contract with outside pharmacies (who are not covered entities) to distribute 340B drugs to their patients. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 74 Fed. Reg. 10,272 (Mar. 5, 2010); Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996). "A covered entity that wishes to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between itself and a specified pharmacy." 74 Fed. Reg. at 10277. But it is still the covered entity, not the pharmacy, that participates in the 340B program. As such, the covered entity must "purchase the drug, maintain title to the drug and assume responsibility for establishing its price[.]" *Id.* The contract pharmacy is simply "an agent of the covered entity with the authorization to 'dispense 340B drugs to patients of the covered entity pursuant to a prescription.'" *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136, 1142 (8th Cir. 2024).

340B does not dictate the price covered entities must charge patients for drugs received under the program. But that does not mean covered entities are free to do whatever they like with the discounted drugs they receive. *See Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 700 (3d Cir. 2023) ("Though Section 340B's substantive requirements and restrictions are few, its compliance provisions are many."). Federal law expressly prohibits the resale or transfer—often called "diversion"—of 340B drugs to "a person who is not a patient of [a covered] entity." 42 U.S.C. § 256b(a)(5)(B); *see McClain*, 95 F.4th at 1142 ("covered

entities may not engage in diversion of covered outpatient drugs through 'resell[ing] or otherwise transfer[ring]'" 340B drugs). Covered entities are further prohibited from requesting or receiving "duplicate discounts or rebates" that may be available for drugs obtained via 340B. 42 U.S.C. § 256b(a)(5)(A).

Failure to comply with these strictures subjects both drug manufacturers and covered entities to punishment. Those that "fail to comply can be fined, and covered entities can be kicked out of the program." *McClain*, 95 F.4th at 1142 (quoting *Sanofi Aventis* 58 F.4th at 700). The statute provides two enforcement mechanisms. "Both the Secretary of HHS and drug manufacturers are authorized to audit covered entities to ensure compliance with the diversion and duplicate rebate provisions." *McClain*, 95 F.4th at 1142 (citing 42 U.S.C. § 256b(a)(5)(C)).

II. Plaintiffs are drug manufacturers who have chosen to participate in the 340B program. Filing No. 1, ¶¶ 24–28. As alleged in their complaint,[4] Plaintiffs contend that many covered entities have acted in tandem with contract pharmacies to sell discounted 340B drugs at full price to buyers who are not their patients or otherwise improperly request (and share in the proceeds of) rebates and reimbursements from the sale of discounted 340B drugs. *See* Filing No. 1, ¶¶ 44, 61–72. This widespread diversion—"unlawful distributions to ineligible patients," *id.* at 70—Plaintiffs allege, has allowed "covered entities and commercial [contract] pharmacies to reap [a] windfall[]" and "profit from the diversion Congress intended to prohibit," *id.* at 70, 71.

[4] At the motion to dismiss stage, the facts alleged in the complaint are accepted as true. *Ingram v. Arkansas Dep't of Correction*, 91 F.4th 924, 926 (8th Cir. 2024).

In response to this alleged diversion, Plaintiffs (and other drug manufacturers) began to contractually limit the amount and type of pharmacies covered entities could utilize to dispense 340B drugs. Filing No. 1, ¶¶ 76–78, 80. For example, if a covered entity has an "in-house pharmacy" Plaintiff AbbVie will only "take orders" of 340B drugs "for th[a]t in-house pharmacy." *Id.* at 78. If a covered entity does not have an in-house pharmacy, AbbVie will ship 340B drugs to only one contract pharmacy, which must be located within 40 miles of the covered entity. *Id.* Plaintiffs also sometimes condition the delivery of 340B drugs to contract pharmacies on a covered entity's participation in various information sharing arrangements regarding "340B utilization" at the contract pharmacy location. *Id.*

III. In April 2025 the Nebraska Legislature enacted L.B. 168—the 340B Contract Pharmacy Protection Act. *See* L.B. 168, 109th Leg., 1st sess. (2025) (enacted). L.B. 168 prohibits drug manufacturers from "deny[ing], restrict[ing], or prohibit[ing]" the delivery or receipt of 340B drugs by a contract pharmacy authorized to dispense those drugs on behalf of a covered entity. L.B. 168, § 3(1). This prohibition, however, does not apply if the contract pharmacy's "receipt of such 340B drug is prohibited by federal law." *Id.* L.B. 168 also prohibits manufacturers from requiring covered entities "to submit any data, including any claim data, utilization data, encounter data, medical data, purchasing data, or other data, as a condition for" dispensing a 340B drug to the entity or a contract pharmacy. L.B. 168, § 3(2). As with the former provision, it does not apply if "such data is required by federal law." *Id.* Indeed, L.B. 168 explicitly declares that "nothing" in the act should be "construed or

applied to conflict with federal law." *Id.* § 5.[5] Finally, the statute empowers the Attorney General of Nebraska, as well as Nebraska county attorneys, to sue to enjoin any violation by a manufacturer. L.B. 168, § 4.

L.B. 168 is aimed at maintaining a healthcare infrastructure that provides access to low-income, rural, and other often underserved Nebraskans. As L.B. 168's sponsoring legislator explained, L.B. 168 is designed to help healthcare providers in impoverished and underserved areas "stretch their scarce resources and meet the needs of their patients." Transcript, Banking, Commerce and Insurance Committee, 109th Neb. Leg., 1st Sess., p. 57 (Feb. 4, 2025).[6] "Savings from the 340B program help . . . Nebraska hospitals provide more comprehensive care for underserved patients." *Id.* at 55. L.B. 168, therefore, "helps our local community hospitals, our local pharmacies, and safety net healthcare providers." *Id.* at 57. There can be little doubt that a law with these aims—"advancing the public's health, safety, and welfare"—is a legitimate exercise of Nebraska's sovereign police power. *N'Da v. Golden*, 318 Neb. 680, 705 (2025); *see also State v. Geest*, 118 Neb. 562 (1929).

IV. Here, Plaintiffs have sued the Attorney General of Nebraska, asking that L.B. 168 be declared unconstitutional and seeking an injunction against its enforcement. Filing No. 1, at p. 54–55. The Complaint advances four claims. Claim One alleges L.B. 168 is an unconstitutional taking that violates the Fifth and

[5] *See also* Transcript, Banking, Commerce and Insurance Committee, 109th Neb. Leg., 1st Sess., p. 56 (Feb. 4, 2025) ("LB168 does not seek to change the federal 340B program. It can't.").

[6] Available at: https://www.nebraskalegislature.gov/FloorDocs/109/PDF/Transcripts/Banking/2025-02-04.pdf.

Fourteenth Amendments. Filing No. 1, ¶¶ 119–127. Claim Two contends it is preempted by federal law. *Id.* ¶¶ 128–144. Claim Three alleges that the act violates the dormant Commerce Clause. *Id.* ¶¶ 145–161. Claim Four asserts that L.B. 168 is unconstitutionally vague. *Id.* ¶¶ 161–167.

Attorney General Hilgers seeks dismissal of the Plaintiffs' complaint in its entirety. As explained below, the Plaintiffs have failed to plausibly assert a claim upon which relief can be granted and the claims against Attorney General Hilgers must be dismissed.

LEGAL STANDARD

A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This requires a plaintiff to plead "enough facts to state a claim to relief that is plausible on its face." *Corrado v. Life Inv'rs Ins. Co. of Am.*, 804 F.3d 915, 917 (8th Cir. 2015) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

When a complaint fails to plausibly allege "a claim upon which relief can be granted" it is susceptible to a motion to dismiss. Fed. R. Civ. P. 12(b)(6). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Barton v. Taber*, 820 F.3d 958, 964 (8th Cir. 2016) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Zink v. Lombardi*, 783 F.3d 1089, 1098 (8th Cir. 2015) (quoting *Iqbal*, 556 U.S. at 678). While factual allegations

must be accepted, the court need not accept the truth of a "legal conclusion couched as a factual allegation." *Brown v. Green Tree Servicing* LLC, 820 F.3d 371, 373 (8th Cir. 2016) (quoting *Iqbal*, 556 U.S. at 678). Ultimately, a plaintiff's pleading must "give rise to an entitlement to relief" that rises above "the speculative level." *Usenko v. MEMC LLC*, 926 F.3d 468, 472 (8th Cir. 2019). A complaint in which the factual allegations do not give rise to a plausible claim for relief under "any legal theory" must be dismissed. *See Topchian v. JPMorgan Chase Bank, N.A.,* 760 F.3d 843, 849 (8th Cir. 2014).

ARGUMENT

I. Plaintiffs Have Not Plausibly Alleged a Takings Claim.

Plaintiffs allege that L.B. 168 violates the Takings Clause of the Fifth Amendment (applied to the States via the Fourteenth Amendment),[7] which provides that "private property [shall not] be taken for public use, without just compensation." U.S. Const. Amend. V; *see* Filing No. 1, ¶¶ 124–125, 127. States can "take[]" property in one of two ways: a physical appropriation (sometimes called a "per se" or "classic" taking) or a regulatory taking. *Cedar Point Nursery v. Hassid*, 594 U.S. 139 (2021). When a taking occurs, it entitles the property owner to just compensation. *Id.*

Plaintiffs allege that L.B. 168 is a per se taking of their property (the drugs they produce and sell) for private use. Filing No. 1, ¶ 124. Alternatively, they argue L.B. 168 effectuates a "partial regulatory taking." *Id.* ¶ 125. It is neither.

[7] *See, e.g.*, *Sheetz v. Cty. of El Dorado, California*, 601 U.S. 267, 276 (2024).

A. L.B. 168 does not appropriate Plaintiffs' property.

A classic or per se taking occurs "[w]hen the government physically acquires private property for a public use," including "when the government physically takes possession of property without acquiring title to it." *Cedar Point Nursery*, 594 U.S. at 147. Plaintiffs allege that L.B. 168 constitutes a per se taking because it "require[s] manufacturers to transfer their property at steeply discounted prices to other private entities." Filing No. 1, ¶ 17. They go on to suggest that L.B. 168 *requires* "manufacturers to provide their drugs to other private entities . . . at below-market prices." *Id*. at ¶ 124. This "state-law obligation attached to the federal 340B scheme," they conclude, constitutes a per se taking. *Id*.

That claim fails for two straightforward reasons. *First,* L.B. 168 does not appropriate Plaintiffs' property or drain it of all its value. *Second*, Plaintiffs voluntary participation in the 340B program forecloses any takings claim.

1. The per se takings claim fails at the threshold because L.B. 168 does not *impose* anything on the Plaintiffs with regard to the ultimate ownership, title, disposition, or economic value of their drugs. *See Alimanestianu v. United States,* 888 F.3d 1374, 1380 (Fed. Cir. 2018) ("To find a per se taking, there must be either a permanent physical invasion . . . or a denial of all economically viable uses of the property.") (internal citations). Simply put, L.B. 168 is not a per se taking because no taking has occurred at all. Neither Nebraska nor the Federal Government have seized Plaintiffs' drugs. Nor has either sovereign *mandated* that Plaintiffs sell their drugs to any particular entity at any particular (non-market) price. Quite the contrary, the Federal Government, via enactment of 340B, has offered Plaintiffs a choice. *See*

Novartis, 102 F.4th at 455. To be sure, the structure of that choice is a "powerful incentive" obviously designed by Congress to "induce drug manufacturers" to choose "participation in the 340B program." *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 50 (D. Del. 2021). But this no Hobson's choice; manufacturers are free to decline to participate and, if they so choose, there remains a massive non-government payer market in which they are free to sell their drugs.[8]

The same logic applies to L.B. 168. Nothing in Nebraska's law *dictates* that drug manufacturers participate in the 340B program. As another federal district court (addressing a Missouri law very similar to L.B. 168) recently explained, state-level 340B companion statutes do "not create any new obligation outside of the federal 340B program except with regard to delivery and acquisition of 340B drugs *to contract pharmacies*." *Astrazenca Pharms. LP v. Bailey*, No. 2:24-CV-04143-MDH, 2025 WL 644285, at *6 (W.D. Mo. Feb. 27, 2025) (emphasis added). Indeed, even Plaintiffs acknowledge this baseline reality. In their complaint they recognize that L.B. 168 "cannot exist except in the context of the federal 340B program . . . if the federal program were repealed tomorrow, Nebraska's law would become a . . . nullity." Filing No. 1, ¶ 97. It necessarily follows that if 340B is not a per se taking (and it is not), L.B. 168 is not one either.

[8] *Cf. Bowles v. Willingham*, 321 U.S. 503, 517 (1944) (rejecting a takings claim against a World War II-era price control statute that set a maximum allowable rent in certain geographic areas because it expressly provided that "nothing in this Act shall be construed to require any person to sell any commodity or to offer any accommodations for rent" and there was "no requirement that the apartments in question be used for purposes which bring them under the Act").

2. But even if participation in 340B could be understood, conceptually, as effectuating some sort of taking, Plaintiffs takings claim would still fail because "no deprivation of property occurs when the government places conditions on participation in a voluntary government program." *Boehringer Ingelheim Pharms., Inc. v. United States Dep't of Health & Hum. Servs.*, No. 3:23-CV-01103 (MPS), 2024 WL 3292657, at *14 (D. Conn. July 3, 2024).

Eighth Circuit precedent confirms this principle. In *Minnesota Association of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, the Eighth Circuit rejected a takings claim aimed at a Minnesota law which "as a condition of participation in the state's Medicaid program" limited the "the rates nursing homes may charge residents who do not receive state medical assistance benefits." 742 F.2d 442, 444 (8th Cir. 1984). As the Eighth Circuit explained, when participation in a government program is voluntary, there "simply [is] not . . . a forced taking of property by the state." *Id.* at 446. That was so in *Minnesota Association* "[d]espite the strong financial inducement [affected nursing homes had] to participate in Medicaid." *Id.* If the nursing homes pursuing the takings claim found the statutorily mandated reimbursement rates to be economically unviable, they were free to "terminate their relationship with Medicaid." *Id.* And, in turn, "[t]his voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation." *Id.* The Eighth Circuit has since reiterated and relied on this principle on several occasions.[9]

[9] *See, e.g.*, *Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016); *Key Med. Supply, Inc. v. Burwell*, 764 F.3d 955, 965 (8th Cir. 2014). Other circuits agree. *See*

To be sure, Plaintiffs have not chosen to "participate" in L.B. 168. But that is beside the point. As the Eighth Circuit recently recognized (and as is discussed in detail below), States are permitted to enact statutes that "supplement" the federal 340B program. *McClain*, 95 F.4th at 1143. And because (as Plaintiffs themselves recognize, *see* Filing No. 1, ¶ 97) L.B. 168 and 340B only operate in tandem, it is the decision to participate in 340B that matters. Because the Plaintiffs' participation in 340B is voluntary, so too is the impact of L.B. 168. If ever Plaintiffs desire to relieve themselves of the obligations that flow from L.B. 168, they can do so by ceasing their participation in 340B. Concomitantly, this voluntariness "forecloses the possibility that [L.B 168] could result in a[] . . . taking." *Minnesota Association*, 742 F.2d at 444.

B. L.B. 168 is not a regulatory taking.

Plaintiffs also argue the L.B. 168 effectuates a regulatory taking. Filing No. 1, ¶ 125. That claim fails for many of the same reasons articulated above. *Minnesota Association*, after all, did not involve a seizure, trespass, or other direct physical invasion or appropriation of any private property. But the "voluntariness precludes a

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Baker Cty. Med. Servs., Inc. v. U.S. Atty. Gen., 763 F.3d 1274, 1276 (11th Cir. 2014) ("[A] long line of cases instructs that no taking occurs where a person or entity voluntarily participates in a regulated program or activity[.]"); *Franklin Mem'l Hosp. v. Harvey,* 575 F.3d 121, 129 (1st Cir. 2009) ("Of course, where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking."); *Garelick v. Sullivan,* 987 F.2d 913, 916 (2d Cir. 1993) ("[W]here a service provider voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and thus there can be no taking."); *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991) ("Governmental regulation that affects a group's property interests does not constitute a taking of property where the regulated group is not required to participate in the regulated industry.") (internal quotation marks omitted).

taking" principle applies with equal force no matter what type of taking is alleged.[10] That said, Plaintiffs' claims fail for the additional reason that they have not alleged sufficient facts to satisfy the balancing inquiry used when assessing an alleged regulatory taking.

A regulatory taking occurs when a regulation "goes too far" in limiting an owner's use of their property. *See Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393 (1922). In *Penn Central Transportation Co. v. New York City*, the Supreme Court established a three-factor test for determining if government action constitutes a regulatory taking. 438 U.S. 104, 124 (1978). Under that framework courts consider: (1) the economic impact of the regulation, (2) the extent to which the regulation has interfered with investment backed expectations, and (3) the "character of the governmental action." *Id*. Applying *Penn Central* to facts alleged here, Plaintiffs have failed to plausibly allege that L.B. 168 is a regulatory taking.

[10] The division between a "classic" or "per se" taking and a "regulatory" taking is not always perfectly clear. *See Maryland Shall Issue, Inc. v. Hogan*, 963 F.3d 356, 365 n.4 (4th Cir. 2020) (Maj. Op) (explaining that "[al]though a 'per se' taking originally only applied to physical takings, the Supreme Court has held that regulatory takings, too, can be per se. For this reason, we refer herein to 'classic' takings as physical takings, which are distinct from regulatory takings"); *id*. at 371 n.4 (Richardson, J., concurring in part) (noting that "'regulatory takings' need not arise from federal-registrar-type 'regulations'" and "laws or other forms of government action [can] result[] in 'regulatory takings.'"). In general, when the government action at issue is physical—a seizure, trespass, or other tangible invasion—a "classic" taking has occurred; in contrast, when government action has more of a metaphysical impact, such as when the application of a statute, regulation, or other government policy has caused a diminishment in the value of property, a "regulatory" taking has taken place. *See Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 321–25 (2002).

There are relatively few non-conclusory allegations in the Complaint that lend support to Plaintiffs' regulatory takings argument. Reduced to its essence, the Plaintiffs' theory of harm is that L.B. 168 facilitates an unconstitutional "A-to-B transfer[]" of wealth in which "deeply discounted" 340B drugs sold to covered entities are resold by contract pharmacies at "regular" or "full" prices to non-indigent customers, with the difference ("the spread") split between covered entities and their pharmacy business partners. *See* Filing No. 1, ¶¶ 42, 58, 67, 68, 108.

As discussed above, these are allegations of diversion, a practice that is expressly forbidden by federal statutory scheme that governs the 340B program. 42 U.S.C. § 256b(a)(5)(B); *see also McClain*, 95 F.4th at 1142. Plaintiffs themselves recognize that diversion is unlawful. *See* Filing No. 1, ¶ 41 (acknowledging that the "federal 340B statute [is] structured to prevent" covered entities from "profiting from the sale of manufacturers' drugs at discounted prices"); *id.* at ¶ 44 (federal law "expressly forbids 'diversion'"). Plaintiffs do not directly allege the size of the harm *they specifically* have suffered from diversion. The closest they come is a notation that there was more than $66 billion in 340B drug purchases during fiscal year 2023 nationwide. *See id.* at ¶ 114. That is paired with the nonspecific contention that AbbVie's losses from diversion exceed the entirety of Nebraska's "anticipated biannual revenue," *id.* at 115,[11] and the conclusory assertion that L.B. 168 "imposes significant financial losses on AbbVie and other manufacturers," *id.* at 127.

[11] The comparison is misleading at best and disingenuous at worst. Highlighting that there have been $66.3 billion in sales of discounted drugs across the entire 340B program says very little about the value of sales that have occurred *in Nebraska*. And aggregate sales figures indicate even less about the extent of diversion that may or may not have occurred in

These allegations do not plausibly establish that L.B. 168 is a regulatory taking. At the threshold, it is essential to remember that L.B. 168 *does not authorize diversion*. Thus, the primary harm that Plaintiffs has alleged—lost sales revenue—is attributable to the wrongful actions of the diverting third parties, not conduct authorized or required by L.B. 168. That matters because "a regulatory taking does not occur unless there are serious financial consequences that stem *from the government action*." *Piszel v. United States*, 833 F.3d 1366, 1378 (Fed. Cir. 2016) (emphasis added). The disconnect between the source of the alleged harm and L.B. 168 is apparent on the face of Plaintiffs' pleading. In the Complaint, they highlight various media exposés and government reports concerning diversion by covered entities and contract pharmacies. *See* Filing No. 1, ¶¶ 69–75. But, at the risk of stating the obvious, L.B. 168 was obviously not the cause of diversion that occurred *before its enactment*.

To be sure, Plaintiffs allege that enforcement of L.B. 168 will prevent them from adopting (or require them to abandon) policies designed to prevent or otherwise mitigate against ongoing or future diversion; in other words, L.B. 168 limits their ability to engage in "self-help." *See* Filing No. 1, ¶¶ 76–78, 80, 89, 95. But even if that is true, it is the parties engaged in diversion—not the State of Nebraska—that are responsible for any resulting economic burden. When applying the *Penn Central*

Nebraska; on that front, the Complaint is *silent*. But even if one assumes that L.B. 168 facilitates diversion—a highly-contested premise—it would blink reality to suggest that L.B. 168, a regulatory scheme that applies only within Nebraska's borders, could somehow be the proximate cause of the multi-billion-dollar economic burden Plaintiffs imply they have suffered *nationwide*.

factors, this Court should focus on the burdens that flow directly from the government action at issue, not tangential impacts, attributable to third parties, that may indirectly arise. *See St. Bernard Par. Gov't v. United States*, 887 F.3d 1354, 1361 (Fed. Cir. 2018) ("In both physical takings and regulatory takings, government liability has uniformly been based on affirmative acts by the government or its agent.").

Nor can it be ignored that there exists a pathway to reduce whatever ancillary economic burden might be, in theory, indirectly attributable to L.B 168. Federal law authorizes audits by both drug manufacturers and the Secretary of HHS. U.S.C. § 256b(a)(5)(C). And HHS has the power to punish covered entities who engage in diversion, a power that includes the ability to award manufacturers "monetary penalties"—effectively restitution—for losses attributable to diversion. *Id.* at (a)(5)(D); *see also id.* at (d)(2), (3). Thus, to the extent 340B diversion is imposing an economic burden on Plaintiffs, their gripe is with the enforcement priorities and efficacy of federal HHS, not the State of Nebraska.

That said, even assuming that some economic burden could be properly attributed to L.B. 168, the allegations in Plaintiffs' complaint are insufficient. The test for evaluating a purported regulatory taking requires courts "to compare the value that has been taken from the property with the value that remains in the property." *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 497 (1987). Thus, when evaluating the economic burden, one of the "critical questions" is "how to define the unit of property" and, in particular, what value is "to furnish the denominator of the fraction." *Id.* In other words, determining whether government

action imposes such an economic burden that it "goes too far," *Mahon*, 260 U.S. at 415, requires a particularized understanding of both the economic activity being burdened and the size of that burden.

Plaintiffs' Complaint provides neither half of the relevant fraction. Indeed, the Complaint does not even seem to recognize the need to sketch out the equation. It contains no allegations about the revenue Plaintiffs earn (not from drug sales in general, nor the sale of 340B drugs in particular, and certainly nothing about drugs sales that actually take place in Nebraska), no allegations concerning profits margins, no allegations about the amount of diversion that takes place in Nebraska, nor anything about the amount of loss incurred (not even a ballpark estimate). In short, Plaintiffs have not sufficiently pled the facts necessary to plausibly show that L.B. 168 imposes the sort of economic burden necessary to qualify as a regulatory taking.

Plaintiffs have also failed to plead sufficient facts to satisfy the remaining two *Penn Central* factors. The Complaint declares—without additional explanation or burnishment—that L.B. 168 "interferes with drug manufacturers' reasonable investment backed expectations." Filing No. 1, ¶127. Of course, this sort of unsupported conclusory statement need not be credited simply because it is couched as a factual allegation. *Green Tree Servicing*, 820 F.3d at 373. And the Complaint is bereft of any other allegations that concern this factor.

Similarly, with respect to the character of the government action, the Complaint merely concludes that L.B. 164 "serves no valid government purpose because it deprives manufacturers of the full use and control of their property on a

continual basis for the commercial benefit of private parties." Filing No. 1, ¶ 127. But that pablum could be said about nearly *any* regulatory scheme. Regulations, by their very nature, often restrict the behavior of some parties in order to preserve the rights or even provide a benefit to others. But, so long as a regulatory scheme promotes "public safety, health, morals" or the "general welfare" and otherwise fits within constitutional constraints, it is an appropriate exercise of Nebraska's police power and its purpose is legitimate. *See Geest*, 118 Neb. at 562; *see also N'Da*, 318 Neb. at 703. Plaintiffs have, for the reasons discussed above and below, failed to establish that L.B. 168 violates the Constitution. And they have alleged nothing that plausibly establishes that the character or nature of L.B 168 is in any way inappropriate.

II. Plaintiffs Have Not Alleged a Plausible Preemption Claim.

Plaintiffs allege that L.B. 168 is preempted by federal law. *See* Filing No. 1, ¶¶ 128–144. They advance two theories—field and conflict preemption. *Id*. Both fail.

The ultimate touchstone of preemption analysis is "the purpose of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). As the Supreme Court has explained on numerous occasions, when Congress has "legislated . . . in a field which the States have traditionally occupied" the analysis begins with "the assumption that the historic police powers of the States were not to be superseded" unless doing so was the "clear and manifest purpose of Congress." *Id*.; *see also Wyeth v. Levine*, 555 U.S. 555, 564-65 (2009). The "practice of pharmacy is an area traditionally left to state regulation." *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021).

Therefore, Plaintiffs must plead compelling facts that show it was Congress's intent that 340B "state supplement" laws like L.B. 168 are preempted. They have not—and cannot—do so, because those facts do not exist.

A. Congress did not preempt the field.

Field preemption prevents States from regulating in an arena where "a federal regulatory scheme occupies the field because of its pervasive nature." *McClain*, 95 F.4th at 1143. When "Congress evidences an intent to occupy a given field, any state law falling within that field is preempted." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984). A party claiming field preemption must establish that Congress "intended to foreclose any state regulation in the area, irrespective of whether state law is consistent or inconsistent with federal standards." *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377 (2015) (quoting *Arizona v. United States*, 567 U.S. 387, 401 (2012)).

Plaintiffs' field preemption argument can be quickly cast aside because it has very been recently rejected by the Eighth Circuit. In *McClain*, a trade association of drug manufacturers argued that Arkansas's 340B state law supplement was unconstitutional because "the 340B Program preempts the field." 95 F.4th at 1143. That argument was rejected out of hand. "[T]he 340B Program is not 'so pervasive . . . that Congress left no room for the States to supplement it.'" *Id.* (quoting *Arizona*, 567 U.S. at 399). The Court explained that "[p]harmacies have always been an essential part of the 340B Program. Yet, the text of 340B is silent about delivery of drugs to patients." *Id.* (internal quotation marks omitted). This silence, contrasted with the federal scheme's "provisions that directly address distribution by third-party wholesalers," *id.*, left little doubt about Congress's intent. "Congress's decision not to

legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field." *Id.*[12]

Plaintiffs' argument that L.B. 168 interferes with the "federal oversight structure by undermining federal enforcement authority," Filing No. 1, ¶ 141, does not change the calculus. That argument was considered and rejected in *McClain*. The trade association there claimed that Arkansas' law intruded on the "detailed oversight apparatus housed within HHS." Appellant Br. at 29, *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024) (No. 22-3675), 2023 WL 2337833. But the Eighth Circuit held that HHS's authority under the 340B program to "address[] discount pricing," did not preempt state officials' different authority to "ensure[] that covered entities can utilize contract pharmacies for their distribution needs." *Id.* No matter the argument, *McClain* controls on the question of field preemption.

B. Nothing prevents Plaintiffs from complying with both federal law and L.B. 168.

Federal law preempts state law under "conflict" (also sometimes called "impossibility" or "obstacle") preemption where a person's "compliance with both state and federal law is impossible" or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *McClain*, 95 F.4th at 1140. Conflict preemption requires "the identification of [an]

[12] Other courts that have addressed the issue agree—there is no indication that Congress intended for 340B to preempt the field. *See AstraZeneca Pharms. LP v. Fitch*, No. 1:24CV196-LG-BWR, 2024 WL 5345507, at *6 (S.D. Miss. Dec. 23, 2024); *Pharm. Rsch. & Manufacturers of Am. v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *8 (W.D. La. Sept. 30, 2024).

'actual conflict'" between a state and federal law. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 884 (2000) (citing *English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990)).

1. It is manifestly *not* impossible for drug manufacturers comply with both L.B. 168 and federal law governing the 340B program. Plaintiffs allege that L.B. 168 "force[s] them to transfer their discounted drugs to any location authorized by a covered entity—even if it contradicts federal law." Filing No. 1, ¶ 132. This contention cannot be squared with L.B. 168's plain language. Nebraska's law prohibits manufacturers from withholding 640B drugs from contract pharmacies "*unless receipt of such 340B drug is prohibited by federal law*." L.B. 168 § 3(1) (emphasis added). Necessarily, then, if distribution to a contract pharmacy would violate federal law, L.B. 168 does not require it. Accordingly, Nebraska law *never* requires a manufacturer to distribute 340B drugs in violation of federal law. *Cf. McClain*, 95 F.4th at 1146 (rejecting conflict preemption claim against Arkansas's 340 supplement statute because plaintiffs failed establish that "simultaneous compliance with state and federal law impossible"); *Astrazenca Pharms.*, 2025 WL 644285, at *3 (same).

L.B. 168's restrictions on conditioning delivery on the receipt of data from covered entities also do not require manufacturers to violate federal law. The law prohibits drug manufacturers from requiring a covered entity to submit data to the manufacturer as a condition for acquiring a 340B drug, "unless such data is required by federal law." L.B. 168 § 3(2). Thus, whenever federal law *requires* data be provided, a manufacturer can demand that data from a covered entity. So, again, L.B. 168 does

not prohibit manufacturers from imposing a condition on covered entities that is necessary for manufacturers to comply with federal law.

Furthermore, for good measure, L.B. 168 contains a savings clause designed to ensure that it does not interfere with federal law; that clause requires any ambiguity to be interpreted in alignment with the relevant federal statutes. "Nothing in [L.B. 168] shall be construed or applied to conflict with federal law[.]" L.B. 168, § 5.

2.a. Plaintiffs also allege that L.B. 168 is preempted under "obstacle" conflict preemption because it frustrates Congress's safeguards against diversion. Filing No. 1, ¶ 133. As discussed above, "diversion" occurs when a covered entity illegally "resell[s] or otherwise transfer[s] the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Plaintiffs allege that L.B. 168 "forc[es] manufacturers to support" diversion by "forc[ing] manufacturers to transfer their drugs under the 340B program at deeply discounted prices to any entity." Filing No. 1, ¶ 133.

Just as with field preemption, the Eighth Circuit has already rejected this theory. In *McClain*, the Court considered an obstacle preemption challenge to Arkansas' 34B supplement statute. 95 F.4th at 144. The trade association plaintiff there argued that Arkansas' law facilitated diversion by requiring drug manufacturers to "distribute 340B-discounted drugs to any and all contract pharmacies." Appellant Br. at 13, 25, *McClain*, 95 F.4th 1136 (No. 22-3675), 2023 WL 2337833.

The Eighth Circuit found no obstacle. "The delivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle" to either a manufacturer or covered entity compliance with Congress's wishes. *McClain*, 95 F.4th at 1145. Nothing in the law "require[s] manufactures to provide 340B pricing discounts to contract pharmacies." *Id.*; *contra* Filing No. 1, ¶ 132–133. Instead, the Court recognized, state supplement statutes merely prevent "pharmaceutical manufacturers from interfering with a covered entity's contract pharmacy arrangements." 95 F.4th at 1145.[13] Thus, *McClain* controls here.

Moreover, as discussed above, L.B. 168 does not authorize or encourage either covered entities or contract pharmacies—or anyone else—to engage in diversion. Nor does it shield those who engage in diversion from legal consequence. Thus, Plaintiffs' suggestion that L.B. 168 "directly conflict[s] with" the federal statute's "prohibition against diversion," Filing No. 1, ¶ 102 cannot be squared with what L.B. 168 actually says. The anti-diversion mechanisms built into the federal statutory scheme are not at all inhibited by L.B. 168. Indeed, as evidenced by the savings clause and other reservation language noted above, L.B. 168 goes out of its way to avoid conflict with federal law. Plaintiffs' allegations and argument to the contrary are not plausible.

b. Plaintiffs also allege that the L.B. 168's restriction on conditioning delivery on the provision of data "obstructs the objectives of the federal 340B program." Filing No. 1, ¶ 135. They claim that "manufacturers cannot satisfy federal audit requirements without providing data-backed 'reasonable cause' for [HHS] to

[13] *Accord Astrazenca Pharms.*, 2025 WL 644285, at *2–3; *AstraZeneca Pharms. LP*, 2024 WL 5345507, at *5; *Murrill*, 2024 WL 4361597, at *9.

audit a covered entities' 340B compliance." Filing No. 1, ¶ 135. These allegations fail to establish obstacle preemption for several reasons.

First, L.B. 168 does not prohibit manufacturers from obtaining data necessary to comply with federal law. Again, Nebraska law does *not* prohibit a manufacturer from requiring covered entities to share or otherwise provide data if "such data is required by federal law." L.B. 168 § 3(2). L.B. 168 thus allows manufacturers to adopt policies that require covered entities to provide any data necessary to comply with federal law.

Second, L.B. 168 only prohibits manufacturers from conditioning *receipt* of a 340B drug on the provision of data. It does not outright prohibit manufacturers from *collecting* or *demanding* data from covered entities related to 340B drugs and drug utilization. That is hardly surprising because federal law *requires* covered entities make certain data available. Covered entities must "permit" drug manufacturers "to audit" covered entities' records "that directly pertain to . . . compliance with [the 340B program]" in order to achieve federal statutory objectives, which include the prevention and remediation of diversion. 42 U.S.C. § 256b(a)(5)(C). Thus, while L.B 168 forbids a manufacturer from telling a covered entity "hand over your data or you do not get 34B drugs," that constraint on *methodology* does not represent an insurmountable obstacle that prevents a manufacturer from obtaining the data they are entitled to obtain under federal law. Thus, L.B. 168 does not "actually conflict" with the federal statutory scheme.

C. Plaintiffs' attempts to distinguish *McClain* fails.

Plaintiffs try to save their preemption arguments in two ways. *First*, they try to distinguish *McClain* by saying L.B. 168 requires manufacturers to transfer title of the drugs to contract pharmacies while the Arkansas' statute did not. Filing No. 1, ¶ 92. This unsupported, threadbare conclusion has no basis in fact or law. Plaintiffs do not point to any language in L.B. 168 that suggests manufacturers or covered entities must transfer *title* of 340B drugs to contract pharmacies. That is because no such language exists.

L.B. 168 makes clear that it is covered entities—not contract pharmacies—that "purchase" 340B drugs. L.B. 168, § 2(1). This is consistent with the dictates of federal law, which requires that only covered entities initially obtain and always retain title of those drugs (until they are dispensed to a consumer). *See McClain*, 95 F.4th at 1142 (citing 61 Fed. Reg. 43,549, 43,553 (Aug. 23, 1996)); *accord* Filing No. 1, ¶ 65. Thus, it would violate federal law for a contract pharmacy—a non-covered entity—to receive the title to 340B drugs. And the text of L.B. 168 is clear: Manufacturers are not required to deliver 340B drugs under any circumstance where doing so would be "prohibited by federal law." L.B. 168, § 3(1).

Second, Plaintiffs try to find (and impliedly ask this Court to adopt) preemption holdings from two out-of-circuit cases that were not about preemption. *See* Filing No. 1, at ¶ 102. Those cases addressed HHS's attempts to impose restrictions on manufacturer delivery conditions *by federal regulation*. The Third Circuit held that HHS lacked authority to promulgate such a regulation because the 340B statute "is silent about delivery" and "nowhere . . . metion[s] pharmacies."

Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs., 58 F.4th 696, 703 (3d Cir. 2023). The D.C. Circuit agreed. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) ("Section 340B is thus silent about delivery conditions."). But nothing in either decision suggests that *state legislatures* were *preempted* from imposing such requirements via statute. *See Murrill*, 2024 WL 4361597, at *9. In fact, the statutory "silen[ce]" central to those holdings confirms and reinforces *McClain*'s holding that "[c]ongressional silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field." 95 F.4th 1136, 1144.

At bottom, *McClain* controls. L.B. 168 is not preempted.

III. Plaintiffs Failed to Plead a Plausible Commerce Clause Claim.

The Commerce Clause grants Congress the power to regulate commerce "among the several states." U.S. Const. art. I, § 8, cl. 3. "The dormant Commerce Clause is the negative implication of the Commerce Clause: states may not enact laws that discriminate against or unduly burden interstate commerce." *S. D. Farm Bureau, Inc. v. Hazeltine*, 340 F.3d 583, 592 (8th Cir. 2003).

A state statute may violate the dormant Commerce Clause in three ways: if it (1) "clearly discriminates against interstate commerce in favor of in-state commerce," (2) "imposes a burden on interstate commerce that outweighs any benefits received," or (3) "has the practical effect of extraterritorial control on interstate commerce." *Grand River Enters. Six Nations, Ltd. v. Beebe*, 574 F.3d 929, 942 (8th Cir. 2009).

Plaintiffs assert L.B. 168 violates the dormant Commerce Clause in each of these three ways. None of their contentions are plausible.

1. First, Plaintiffs claim that L.B. 168 "discriminates against interstate commerce in favor of in-state commerce" by "privileg[ing] state hospitals and pharmacies over out-of-state manufacturers." Not so. While it is true that L.B. 168 imposes burdens on only drug manufacturers, and not covered entities, it does so regardless of whether those entities are located inside or outside Nebraska. *See* L.B. 168, § 3 (statute applies to "*any* manufacturer, agent or affiliate") (emphasis added). And while its scope is likely limited to transactions with in-state covered entities, *see* pp. 31–33, *infra*; *see also State v. Godek*, 312 Neb. 1004, 1016 (2022) (recognizing the presumption that Nebraska "state law has no extraterritorial effect"), it could be applied to in-state covered entities that are subsidiaries of out-of-state parent companies. Thus, because L.B. 168 "grants no 'differential treatment'" between similarly situated in-state and out-of-state parties, it "avoids violation of the dormant Commerce Clause." *Grand River Enters.*, 574 F.3d at 942.

2. Plaintiffs next allege that L.B. 168 imposes a burden on interstate commerce that outweighs any benefit to in-state commerce. Filing No. 1, ¶ 153. Such a claim is evaluated via *Pike* balancing—a state statute is valid under *Pike* if "the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental." *Grand River Enters.*, 574 F.3d at 942 (quoting *Pike v. Bruce Church, Inc.,* 397 U.S. 137, 142 (1970)). A statute will

be upheld "unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Id.* (quoting same).

Plaintiffs allege that L.B 168 imposes a significant economic burden on interstate commerce by making drug manufacturers liable in Nebraska for transactions that occur outside of Nebraska. But L.B. 168 applies only to transactions with covered entities located in Nebraska, and a State is well within its power to regulate delivery to covered entities and pharmacies within its borders. *See* pp. 31–33, *infra*.

Plaintiffs also complain that L.B 168 burdens interstate commerce by allowing covered entities to engage in diversion. Filing No. 1, ¶ 157. Again, the impact of diversion is attributable to the unlawful behavior of third parties, not the State of Nebraska or its laws. *See* pp. 5–6, 16–17, *supra*. Plaintiffs say "they will no longer be able to stop the[se] abuses" because of L.B. 168. Filing No. 1, ¶ 157. But that is simply not true. As discussed above, nothing in L.B. 168 defangs or defeats the substantial anti-diversion provisions embedded in federal law. *See* pp. 7–8, 16–18, 25–26 *supra.* And there can be little doubt that the constitutionality of a state statute cannot turn on whether private parties choose to comply with or violate federal law.

On the other side of the balance, the State no doubt has a legitimate and important public interest here. Regulating the distribution of pharmaceuticals is a "traditional" prerogative of the state. *McClain*, 95 F.4th at 1143. "[W]hen it comes to pharmaceuticals," state law provides an "important[] layer of consumer protection that complements [federal] regulation." *Id.* (quoting *Lefaivre v. KV Pharm. Co.*, 636

F.3d 935, 940–41 (8th Cir. 2011)). L.B. 168 is designed to help ensure that people in rural and other underserved areas have access to critical drugs and the health care those drugs facilitate through a provider proximate to them. In the words of L.B. 168's sponsoring legislator, the law was aimed to helping covered entities "stretch their scarce resources and meet the needs of their patients." Transcript, Banking, Commerce and Insurance Committee, 109th Neb. Leg., 1st Sess., p 57 (Feb. 4, 2025). Any alleged burden on interstate commerce is not "clearly excessive" when balanced against these important state interests.

3. Plaintiffs also complain that L.B. 168 exerts extraterritorial control over transactions in other States. "The Commerce Clause precludes the application of a state statute to commerce that takes place wholly outside of the State's borders[.]" *Styczinski v. Arnold*, 46 F.4th 907, 913 (8th Cir. 2022) (cleaned up) (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989)). Plaintiffs complain that L.B. 168 does not have any language limiting its scope: "[T]he Nebraska law could govern a transaction between a drug manufacturer located in Illinois, its wholesaler in Kentucky, and a California pharmacy that contracts with a covered entity in Florida and dispenses the drug to a Nebraska resident." Filing No. 1, ¶ 161.

But that suggestion is incongruent with Nebraska law. At the threshold, silence does not automatically give rise to a presumption of extraterritoriality. "Ordinarily, no penalty can be incurred under the law of this state except for transactions occurring within this state, and our state law has no extraterritorial

effect." *State v. Karsten*, 194 Neb. 227, 229 (1975). Thus, Plaintiffs' suggestion that silence *necessarily* means a law has extraterritorial reach is precisely backwards.

At most, when a statute is silent regarding its potential extraterritorial application, the appropriate "recourse" is to review "legislative history to determine the intent of the lawmakers." *Harper v. Silva*, 224 Neb. 645, 649 (Neb. 1987). Here, when L.B. 168's legislative sponsor introduced the bill in committee, he made clear that it was aimed at "protect[ing] access to the 340B Community Benefits Program for eligible . . . healthcare providers *in our state*." Transcript, Office Banking, Commerce and Insurance Committee, 109th Neb. Leg., 1st Sess., p. 55 (Feb. 4, 2025) (emphasis added). This statement strongly suggests that L.B. 168 was intended to apply only to a manufacturers' dealings with covered entities located in Nebraska. That would align with the usual understanding of the scope of Nebraska law; in the ordinary course, state statutes apply "to all rights which, and all persons who, *come within the limits of the state*." *Harper*, 399 N.W.2d at 829 (emphasis added); *see also See Kuklenski v. Medtronic USA, Inc.*, 702 F. Supp. 3d 783, 791 (D. Minn. 2023), ("[T]here is a presumption against the extra-territorial application of a state's statutes."), *aff'd*, No. 24-1310, 2025 WL 1063430 (8th Cir. Apr. 9, 2025). At least one other federal court has interpreted a similarly worded statute to apply only to in-state covered entities. *See Murrill*, 2024 WL 4361597, at *11.

Further, limiting L.B. 168's application to covered entities in Nebraska aligns with its express command that it not "be construed or applied to conflict with federal law." L.B. 168, § 5. This Court should not construe statutory silence about L.B. 168's

scope in a manner that would be contrary to this related express indication of legislative intent.

Given that, properly understood, L.B. 168 applies only to the sale and delivery of 340B drugs to covered entities in Nebraska, it does not apply "to commerce that takes place *wholly outside* of the State's borders." *Styczinski*, 46 F.4th at 913 (emphasis added). It therefore does not have the practical effect of controlling commerce outside Nebraska.

IV. Plaintiffs Failed to Plead a Plausible Due Process Claim

Finally, Plaintiffs assert that L.B 168 is unconstitutionally vague. A statute is unconstitutionally vague if it "'fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits' or 'authorizes or even encourages arbitrary and discriminatory enforcement.'" *Crum v. Vincent*, 493 F.3d 988, 994 (8th Cir. 2007) (quoting *Hill v. Colorado*, 530 U.S. 703, 732 (2000)).

Specifically, Plaintiffs complain that L.B. 168 is not clear about who must receive 340B-discounted drugs. They say they are "left to guess" what "any location authorized by any 340B entity to receive such 340B drug" means. Filing No. 1, ¶ 20. *Cf.* L.B. 168, § 3(1). The statute, according to Plaintiffs, could apply to "the lunar surface, low-earth orbit, or a neighborhood pharmacy." Filing No. 1, ¶ 166 (quoting *Novartis*, 102 F.4th at 458).

But L.B 168 draws lines of clarity via its repeated provisos that it does (or does not, as appropriate) apply in circumstances where its application would be "required by," "prohibited," or in "conflict with" "federal law." L.B. 168, § 3(1), (2); § 5. Plaintiffs

can thus look to federal law to determine what locations they can and cannot service. For example, federal law dictates that Plaintiffs not distribute its drugs to places not authorized to receive and distribute them under the strictures of the Controlled Substances Act. *See* 21 U.S.C. § 841(a)(1); *Monson v. Drug Enf't Admin.*, 589 F.3d 952, 956 (8th Cir. 2009). Plaintiffs—whose business is the manufacture of pharmaceuticals, many of which are subject to state and federal control—should have little difficulty determining which entities and locations are authorized to receive drugs under federal law.

Subject to the overarching parameters set by federal law, L.B. 168 requires Plaintiffs to deliver 340B drugs to "any location authorized by any 340B entity to receive such 340B drug." This is not ambiguous. *See Murrill*, 2024 WL 4361597, at *11. Plaintiffs cannot restrict delivery to *any* pharmacy with whom a covered entity legally contracts. Indeed, HHS's 2010 federal guidance regarding contract pharmacies states that a "covered entity has the option of individually contracting for pharmacy services with a pharmacy(ies) of its choice." 75 Fed. Reg. 10278 (March 5, 2010); *see* Filing No. 1, ¶ 53. L.B. 168 simply reflects the Nebraska Legislature's conclusion that permitting that sort of contractual arrangement promotes the health, well-being, and general welfare of Nebraska.

CONCLUSION

Attorney General Hilger's Motion to Dismiss should be granted.

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Respectfully submitted.

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CERTIFICATE OF COMPLIANCE

Pursuant to NE. Civ. R. 7.1(d), the undersigned hereby certifies that the foregoing principal brief contains 9,343 words (including the caption, headings, footnotes, and quotations) in compliance with said rule. The undersigned utilized the word count function of Microsoft Word for Microsoft Office 365.

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